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EXAMINER

SAUD, C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1646 | |

DATE MAILED: 11/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/837,009

Applicant(s)

BELL et al.

Examiner
Christine Saoud

Group Art Unit
1646



☒ Responsive to communication(s) filed on Oct 7, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-41 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Oath/Declaration

2. The reissue oath/declaration filed with this application is defective because it fails to contain a statement that "all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration" arose without any deceptive intention on the part of the applicant. See 37 CFR 1.175 and MPEP § 1414.

3. Claims 1-41 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration was set forth in the previous Office action. Applicant's acknowledgment of the rejection is noted, but does not overcome the rejection because a new declaration has not yet been received.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 6-9, and 14-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions encoding insulin-like growth factors wherein the nucleic acid molecule comprises the sequence of (a) or (b) of claim 1 (including host cells containing said nucleic acid molecule, methods of making a polypeptide from said host cells), does not reasonably provide enablement for nucleic acid molecules encoding an insulin-like growth factor wherein the nucleic acid is complementary to (a) or (b), or wherein the nucleic acid is at least 18 bases in length. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1 is directed to a composition comprising nucleic acid molecules encoding insulin-like growth factor, wherein the nucleic acid has a sequence which is selected from a specified group. Element (c) are nucleic acid sequences which are complementary to those sequence which encode the insulin-like growth factors. Therefore, by definition, the nucleic acid molecule of part (c) of claim 1 cannot encode the polypeptide because it is complementary (i.e. non-coding) and is therefore not enabling for a composition comprising nucleic acid molecules encoding insulin-like growth factor, as required by the claim. This is also true for claims 8 and 18, which contain this same language. Claims 6-7, 9, 14-17, 19-24, 29-31, and 36-41 are dependent from these claims, and are also, therefore, not enabled for the reasons provided above. Applicant has not corrected this deficit by the instant amendment. This ground of rejection could be obviated by not requiring

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the nucleic acid molecule to "comprise an insulin-like growth factor (IGF) sequence" which is interpreted as meaning a coding sequence; i.e. the claim could simply be an isolated nucleic acid molecule selected from the group consisting of: (a) and (b). Then the additional element of a complimentary molecule of (a) or (b) is proper and enabled.

Claim 1 is directed to a composition comprising nucleic acid molecules encoding insulin-like growth factor, wherein the nucleic acid has a sequence which is selected from a specified group. Element (d) are fragments of (a)-(c) "that are at least 18 bases in length". The claim is broader than the enabling disclosure because one of ordinary skill in the art would not reasonably expect a nucleic acid which is only 18 bases in length to encode an insulin-like growth factor protein. The specification only provides for two IGF proteins (IGF-I in Figure 1 and IGF-II in Figure 2). The mature forms of these proteins consist of 70 and 67 amino acids respectively, therefore, there is a minimum number of nucleic acid residues which are required to enable the instant claim because the claim is directed to compositions comprising nucleic acids encoding IGF. This is also true for claims 8 and 18, which contain this same language. Claims 6-7, 9, 14-17, 19-41 are dependent from these claims, and are also, therefore, not enabled for the reasons provided above.

If the claims are amended as suggested above for the complimentary molecule issue, one could use a nucleic acid of 18 bases in length as a probe, and the nucleic acid molecules would be enabled. However, the methods of making a polypeptide would not be enabled because the claims fail to recite a reading frame that would provide for a fragment of the IGF protein. Those

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embodiments which would not result in a fragment of IGF are not enabled by the instant specification as filed, and the claims lack a critical element, which is reading frame, for the methods of making a polypeptide using these nucleic acid molecules (see claims 23-24).

6. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 6 is directed to a molecule which is DNA, however, the claim from which it depends provides for the presence of either U or T in the nucleic acid molecule. The specification is not enabled for the production of a DNA molecule wherein the molecule contains U instead of T. The rejection could be avoided by specifically reciting that the molecule contains T instead of U.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 23-24 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural

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cooperative relationships are: the reading frame of the 18 base pair fragment of the nucleic acid molecule necessary for making a polypeptide.

10. Claims 27-28 are unclear and indefinite because it is not clear what "said polypeptide" is being expressed. The claims are open regarding the nucleic acid molecule that is contained in the host cell due to the comprising language. Therefore, the nucleic acid molecule may encode many proteins. The claims could be reworded such that it is clear that the protein being expressed is the protein encoded by the nucleic acid molecule of claim 4 or 5. For example, the claim could state a method of producing a polypeptide, comprising introducing into a suitable host cell the nucleic acid molecule of claim 4 and expressing the nucleic acid molecule in said host cell. Applicant should again note that it is the nucleic acid molecule which is being expressed, and not the sequence of the molecule.

Conclusion

11. Applicant's statement regarding an interview is acknowledged. However, if Applicant desires an interview, a phone call should be placed prior to submission of a response. Upon filing a response, the Examiner has a set period of time to work on the application which does not afford sufficient time for scheduling and holding of an interview. Additionally, the amendment which has already been entered must be responded to and an interview with a pending amendment for consideration is not timely. Applicant is encouraged to call regarding any questions about amendments to place the claims in condition for allowance. The issues that are outstanding are

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relatively minor in terms of amendments needed to overcome the rejections. However, the issue of a new declaration is still outstanding.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.
November 10, 1999

CA


JOHN ULM
PRIMARY EXAMINER
GROUP 1600